4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-4417]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pharmaceutical Voluntary Consensus Standard Recognition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The title of this information collection is "Pharmaceutical Voluntary Consensus Standard Recognition." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-45, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Pharmaceutical Voluntary Consensus Standard Recognition

OMB Control Number 0910--NEW

This information collection helps support implementation of FDA's Center for Drug Evaluation and Research's (CDER) Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality. The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) and Circular A-119 by the Office of Management and Budget (OMB) have established Federal Government policies to improve the internal management of the executive branch by directing agencies to use voluntary consensus standards developed or adopted by a standards developing organization--rather than Government-unique standards--except where these standards are inconsistent with applicable law or otherwise impractical. We have developed Agency guidance to communicate procedures respondents can follow to submit requests for recognition of a voluntary consensus standard, as well as procedures CDER will follow when a request is received. The draft guidance entitled, "CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality" (February 2019), outlines justifications for why a standard may be recognized wholly, partly, or not at all. (The draft guidance is available on our website at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cders-program-recognition-voluntary-consensus-standards-related-pharmaceutical-quality.)[1] The guidance also communicates that interested parties may request recognition of a standard, allowing CDER to:

- receive a candidate consensus standard, with relevant information (e.g., the scope of the standard and the purpose), from internal or external parties for informal recognition;
- determine whether to informally recognize a standard in whole or in part following an internal scientific evaluation; and

[1] When final, this guidance will represent FDA's current thinking on this topic.

- list the informally recognized standards in a publicly searchable database on FDA's website, accompanied by an information sheet describing the scope and the extent of informal recognition of that standard and other relevant information.

In the *Federal Register* of February 14, 2019 (84 FR 4076), FDA published a 60-day notice announcing the availability of the draft guidance and invited comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

Guidance Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response (Hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Submission of request for recognition of a voluntary consensus standard (page 2, page 5, section B.1)	9	1	9	1	9	$87.12	$784.08

Based on our experience with similar programs, we assume nine respondents will each submit one request for standard recognition annually, and that it will require 1 hour to prepare. We also assume industry wage rates of $87.12, for a total cost of $784.08 annually.

Dated: July 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-16063 Filed: 7/26/2022 8:45 am; Publication Date: 7/27/2022]